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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,614	01/22/2001	Jo Klaveness	REF/Klaveness/054C	9751

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/05/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,614

Applicant(s)

KLAVENESS ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/09/2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,40-44,47-49 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,40-44,47-49 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

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Response to Amendment

The amendment filed 10/09/2002 has been entered. Claims 39, 45, 46, 50-62 and 64 have been canceled. Claims 38 and 63 have been amended.

Response to Arguments

Any previous rejections that have not been reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38, 40-44, 47-49 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,997,898) in view of Schneider (US 5,643,553) and Martin (US 5,891,468), for the reasons set forth in the office action mailed 7/09/2002.

Applicant's arguments filed 10/09/2002 have been fully considered but they are not persuasive.

Applicant asserts that Unger the features of the current claims are only set forth in Unger within long laundry lists and that the motivation to make the necessary selection to arrive at the claimed invention is not present in Unger.

This is not found persuasive Unger clearly teaches the claimed components, most of which are preferred or claimed embodiments in Unger. For example, clearly the invention of Unger is drawn to a targetable diagnostic and/or therapeutic agent in the form of microbubbles, see abstract and claims 14 and 15. Also, the preferred gases include perfluorocarbons, see column 15, lines 7-20. The microbubbles also preferably contain a phospholipid surfactant which form a monolayer, as well as, one or more vectors for intravascular targeting, as is seen by claims 6, 7 and 14-16. Clearly, the invention as claimed by Unger provides the requisite motivation to select such components, which are substantially the same as those claimed.

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Applicant further asserts that Unger does not teach advantages of using a monolayer.

This is not found persuasive because Unger clearly discloses the use of monolayers, as shown by claims 6 and column 24, lines 9+.

Applicant asserts that Unger fails to disclose the use of covalent coupling of lipids to vectors, wherein the vectors bind to receptors that are associated with angiogenesis, inflammation, atherosclerosis or thrombi, as claimed.

This is not found persuasive because Unger teaches the covalent attachment of vectors to the amphiphilic material, see column 11, lines 60+. Such amphiphilic materials include lipid chains. Also, it is well known in the art to covalently attach a targeting moiety to a lipid to provide targeting to analogous vesicles as shown by Schneider and Martin. Unger teaches that various vectors, antibodies, etc. may be used for targeting, and it is well known in the art that targeting thrombi and/or atherosclerosis is beneficial for such vesicle diagnostic and/or therapeutic agents, as shown by Schneider, as set forth in column 9, lines 10+. Also, the use of anti-CD34 (applicant's elected species) for targeting similar diagnostic or therapeutic agents is known as shown by Martin. One of ordinary skill in the art would have been motivated to employ various useful targeting agents, given the general teaching of Unger that such microbubbles may be targeting to any desired target, including intravascular targets.

Applicant asserts that Schneider and Martin only disclose the targeting of bilayers.

This is not found persuasive because Unger clearly teaches that monolayers and bilayers may be targeted in an equivalent manner. Schneider and Martin are only used for teaching specific targeting sites and/or agents and/or that covalent attachment of the targeting agents via a thiol moiety is a well known means of conjugation of a targeting agent to a vesicle. It is noted that Unger also teaches that vectors are conjugated to the microbubbles via a thiol moiety (e.g., applicant's elected linker), as set forth in column 12, lines 36-49.

Conclusion

No claims are allowed at this time.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
November 4, 2002